

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Reissue of:

U.S. Patent No. 5,767,115

Applicants:

Rosenblum et al.

Serial No.:

To Be Assigned

Group Art Unit: 1202

Filed:

To Be Assigned

Examiner:

Granted:

June 16, 1998

For:

Hydroxy-Substituted Azetidinone

Compounds Useful As

Hypocholesterolemic Agents

BOX REISSUE APPLICATION Director of Patents and Trademarks Washington, D.C. 20231

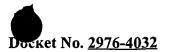
REISSUE APPLICATION DECLARATION BY THE ASSIGNEE

Sir:

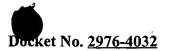
I, as a representative of the assignee Schering Corporation, declare that:

1. I am Staff Vice President and Associate General Counsel, Patents & Trademarks, of Schering-Plough Corporation. I am also Vice President of Schering Corporation, a wholly owned subsidiary of Schering-Plough Corporation. I am authorized to act on behalf of the assignee Schering Corporation with respect to the above-identified reissue application.

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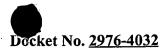
- 2. I certify under 37 C.F.R. § 3.73(b) that Schering Corporation owns the entire right, title and interest in United States Patent No. 5,767,115 ("the '115 patent"). An assignment from the inventors to Schering Corporation was recorded on May 20, 1996 at Reel 7960, Frame 0455. Schering Corporation consents to the filing of the present application for the reissue of U.S. Patent No. 5,767,115.
- 3. I believe that Stuart B. ROSENBLUM, Sundeep DUGAR, Duane A. BURNETT, John W. CLADER and Brian A MCKITTRICK, the named inventors of the '115 patent, are the original, first and joint inventors of the subject matter that is described and claimed in '115 patent granted on June 16, 1998, and for which reissue is sought under 35 U.S.C. § 251.
- 4. I have reviewed and understand the contents of the '115 patent, including the newly-added claim directed to a single compound, namely 1-(4-fluorophenyl)-3(R)-[3(S)-(4-fluorophenyl)-3-hydroxypropyl)]-4(S)-(4-hydroxyphenyl)-2-azetidinone, and newly-added claims directed to a pharmaceutical composition and a method of treatment using the compound. In the patent, the above compound is designated "6A" and is described in Example 6 at column 31, lines 1-10 of the specification and in claim 7 as originally filed and in the issued '115 patent. This reissue application does not seek to enlarge the scope of any of the claims of the original '115 patent.
- 5. I acknowledge the duty to disclose all information which is known to be material to patentability as defined in 37 C.F.R § 1.56. In compliance with that duty, an



Information Disclosure Statement which identifies certain patents and publications listed on PTO-1449 form is being submitted.

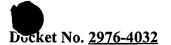
- 6. On behalf of the assignee Schering Corporation, I offer to surrender the '115 patent pursuant to 37 C.F.R. § 1.178.
- 7. All errors corrected in this reissue application up to the filing of the oath or declaration under 37 C.F.R. § 1.175 arose without any deceptive intention on the part of the applicant.
- 8. In accordance with 37 C.F.R. § 1.175(a)(1), I believe that the '115 patent is wholly or partly inoperative or invalid by reason of applicants claiming more or less than they had a right to claim, which error arose without deceptive intention on the part of the applicants and is described below:

An error being relied upon as a basis for this reissue concerns the failure to appreciate the full scope of the invention by not including claims of narrower scope. The error is the failure to include a specific claim to one of the most preferred compounds. Compound 6A is fully described in the specification by structure and method of preparation in the specification in Example 6, beginning at column 31. Finally, compound 6A is one of the compounds listed in originally-filed claim 7, and appears in claim 7 as issued in the '115 patent at column 40, lines 19-21. However, there are presently no claims directed to compound 6A individually.



- 9. As a result of the error in the '115 patent, the following new claims 10-13 are being added in this reissue application:
 - 10. (New) A compound comprising 1-(4-fluorophenyl)-3(R) -[3(S)-(4-fluorophenyl)-3-hydroxypropyl)]-4(S)-(4-hydroxyphenyl)-2-azetidinone
 - 11. (New) A compound represented by the formula:

- 12. (New) A pharmaceutical composition for the treatment or prevention of atherosclerosis, or for the reduction of plasma cholesterol levels, comprising an effective amount of a compound according to claims 10 or 11 in a pharmaceutically acceptable carrier.
- 13. (New) A method of treating or preventing atherosclerosis or reducing plasma cholesterol levels comprising administering to a mammal in need of such treatment an effective amount of a compound according to claims 10 or 11.
- and 11), a pharmaceutical composition for the treatment or prevention of atherosclerosis or for the reduction of plasma cholesterol levels (claim 12), and a method of treating or preventing atherosclerosis or reducing plasma cholesterol levels (claim 13). Claims 10-13 are parallel in form to the original broader claims 7-9, respectively; however, claims 10-13



are narrower in scope in that they are limited to a single compound, a pharmaceutical composition containing this compound and a method of using this compound, respectively.

11. I appoint the following attorneys to prosecute this reissue application, to receive the patent, and to transact all business in the Patent and Trademark Office:

John C. Vassil (Reg. No. 19,098), Alfred P. Ewert (Reg. No. 19,887), David H. Pfeffer (Reg. No. 19,825), Harry C. Marcus (Reg. No. 22,390), Robert E. Paulson (Reg. No. 21,046), Stephen R. Smith (Reg. No. 22,615), Kurt E. Richter (Reg. No. 24,052), J. Robert Dailey (Reg. No. 27,434), Eugene Moroz (Reg. No. 25,237), John F. Sweeney (Reg. No. 27,471), Arnold I. Rady (Reg. No. 26,601), Christopher A. Hughes (Reg. No. 26,914), William S. Feiler (Reg. No. 26,728), Joseph A. Calvaruso (Reg. No. 28,287), James W. Gould (Reg. No. 28,859), Richard C. Komson (Reg. No. 27,913), Israel Blum (Reg. No. 26,710), Bartholomew Verdirame (Reg. No. 28,483), Maria C.H. Lin (Reg. No. 29,323), Joseph A. DeGirolamo (Reg. No. 28,595), Michael P. Dougherty (Reg. No. 32,730), Seth J. Atlas (Reg. No. 32,454), Andrew M. Riddles (Reg. No. 31,657), Bruce D. DeRenzi (Reg. No. 33,676), Michael M. Murray (Reg. No. 32,537), Mark J. Abate (Reg. No. 32,527), Alfred L. Haffner, Jr. (Reg. No. 18,919), Harold Haidt (Reg. No. 17,509), John T. Gallagher (Reg. No. 35,516), Steven F. Meyer (Reg. No. 35,613), Kenneth H. Sonnenfeld (Reg. No. 33,285) and Dorothy R. Auth (Reg. No. 36,434) of Morgan & Finnegan, L.L.P. whose address is: 345 Park Avenue, New York, New York, 10154; and Michael S. Marcus (Reg. No. 31,727) of Morgan & Finnegan, L.L.P., whose address is 1775 Eye Street, Suite 400, Washington, D.C. 20006.

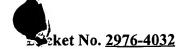
PLEASE SEND CORRESPONDENCE TO:

Richard C. Komson, Esq. Dorothy R. Auth, Esq. Morgan & Finnegan, L.L.P. 345 Park Avenue New York, NY 10154-0053

PLEASE DIRECT TELEPHONE CALLS TO:

Richard C. Komson (212)-415-8562, or Dorothy R. Auth (212)-415-8564





12. I declare that all statements made of my knowledge are true and all statements made on information and belief are believed to be true; and further, that the statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: Sure 4 1600

James R. Nelson

Ataff Vice President, and Associate
General Counsel, Patents & Trademarks
SCHERING-PLOUGH CORPORATION

Vice President SCHERING CORPORATION

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